

§ 184.1903

of this chapter; frozen dairy dessert and mixes as defined in §170.3(n)(20) of this chapter; gelatins, puddings, and fillings as defined in §170.3(n)(22) of this chapter; hard candy as defined in §170.3(n)(25) of this chapter; and soft candy as defined in §170.3(n)(38) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[54 FR 7404, Feb. 21, 1989]

§ 184.1903 Tributyrin.

(a) Tributyrin ($C_{15}H_{26}O_6$, CAS Reg. No. 60-01-5), also known as butyrin or glyceryl tributyrate, is the triester of glycerin and butyric acid. It is prepared by esterification of glycerin with excess butyric acid.

(b) The ingredient meets the specification of the Food Chemicals Codex, 3d Ed. (1981), p. 416, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20005.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice; baked goods as defined in §170.3(n)(1) of this chapter; alcoholic beverages as defined in §170.3(n)(2) of this chapter; nonalcoholic beverages as defined in §170.3(n)(3) of this chapter; fats and oils as defined in §170.3(n)(12) of this chapter; frozen dairy desserts and mixes as defined in §170.3(n)(20) of this chapter; gelatins, puddings and fillings as defined in §170.3(n)(22) of this chapter; and soft candy as defined in §170.3(n)(38) of this chapter.

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(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[54 FR 7404, Feb. 21, 1989; 54 FR 10482, Mar. 13, 1989]

§ 184.1911 Triethyl citrate.

(a) Triethyl citrate ($C_{12}H_{20}O_7$, CAS Reg. No. 77-93-0) is the triethyl ester of citric acid. It is prepared by esterifying citric acid with ethyl alcohol and occurs as an odorless, practically colorless, oily liquid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), p. 339, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, and the Center for Food Safety and Applied Nutrition (HFS-200), 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent as defined in §170.3(o)(12) of this chapter; a solvent and vehicle as defined in §170.3(o)(27) of this chapter; and a surface-active agent as defined in §170.3(o)(29) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section, or different from those set forth in part 181 of this chapter, do not exist or have been waived.

[59 FR 63897, Dec. 12, 1994]

§ 184.1914 Trypsin.

(a) Trypsin (CAS Reg. No. 9002-07-7) is an enzyme preparation obtained from purified extracts of porcine or bovine pancreas. It is a white to tan

amorphous powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.21.4).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32911, June 26, 1995]

§ 184.1923 Urea.

(a) Urea ($\text{CO}(\text{NH}_2)_2$, CAS Reg. No. 57-13-6) is the diamide of carbonic acid and is also known as carbamide. It is a white, odorless solid and is commonly produced from CO_2 by ammonolysis or from cyanamide by hydrolysis.

(b) FDA is developing food-grade specifications for urea in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid as defined in §170.3(o)(14) of this chapter and as a fermentation aid.

(2) The ingredient is used in yeast-raised bakery products; in alcoholic beverages as defined in §170.3(n)(2) of this chapter; and in gelatin products.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51616, Nov. 10, 1983, as amended at 49 FR 19816, May 10, 1984]

§ 184.1924 Urease enzyme preparation from *Lactobacillus fermentum*.

(a) This enzyme preparation is derived from the nonpathogenic, nontoxicogenic bacterium *Lactobacillus fermentum*. It contains the enzyme urease (CAS Reg. No. 9002-13-5), which facilitates the hydrolysis of urea to ammonia and carbon dioxide. It is produced by a pure culture fermentation process and by using materials that are generally recognized as safe (GRAS) or are food additives that have been approved for this use by the Food and Drug Administration (FDA).

(b) The ingredient meets the general and additional requirements for enzyme preparations in the "Food Chemicals Codex," 3d ed. (1981), pp. 107-110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in wine, as defined in 27 CFR 2.5 and 4.10, as an enzyme as defined in §170.3(o)(9) of this chapter to convert urea to ammonia and carbon dioxide.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice. Current good manufacturing practice is limited to use of